PCA

PATIENT MANUAL

ambIT®

AMBULATORY INFUSION THERAPY

MORE THAN PAIN RELIEF…
SUPERIOR PAIN CONTROL

CE 0482 TYPE BF NRTL/C IPX1

SORENSON MEDICAL

Become Familiar with the ambIT® Pump

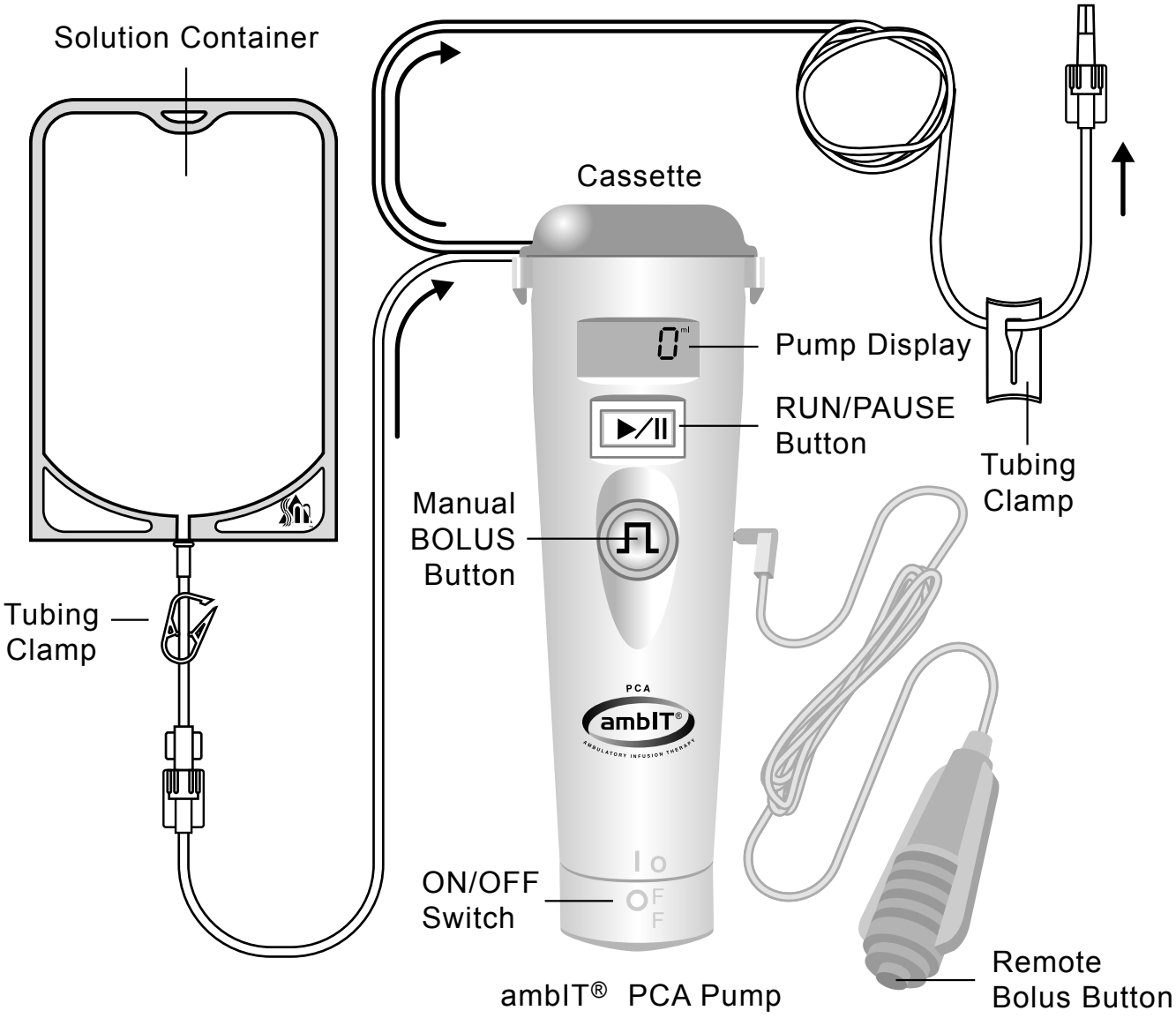


Table of Contents

62089.04 06/05

1.1 Definitions and Symbols

Warning:

A warning message contains special safety emphasis and must be observed at all times. Failure to observe a WARNING message is potentially life threatening.

Caution:

A caution usually appears in front of a procedure or statement. Failure to observe a CAUTION could result in serious patient or user injury.

Note:

A note highlights information that acts as a reminder or helps explain a concept or procedure.

This international symbol means: Attention, consult accompanying documents.

IPX1

Protected from dripping water.

TYPE BF

This is the IEC symbol for TYPE BF equipment.

- IEC Classification Internally Powered.

PCA ambIT AMBULATORY INFUSION THERAPY

- The ambIT® PCA Pump complies with EN 60601-1:1990 including amendments A1 and A2; IEC 60601-1:1998; IEC 60601-2-24:1998; CAN/CSA C22.2 No. 601-M90 with supplement No. 1-94; UL2601-1:1997 with amendments 1 and 2.

CE 0482

This CE symbol certifies that the product complies with the essential requirements of the Medical Device Directive.

NRTL/C

The “NRTL/C” indicator adjacent to the CSA (Canadian Standards Association) Mark signifies the product has been evaluated to the applicable ANSI/UL and CSA standards, for use in the U.S. and Canada. NRTL (Nationally Recognized Testing Laboratory) is a designation granted by the U.S. Occupational Safety and Health Administration (OSHA) to laboratories which have been recognized to perform certification to U.S. Standards.

Do not re-use (Cassettes)

Keep away from heat

Keep dry

Temperature limitation

Sterilized using irradiation

LATEX-free

Indicates which tubing connects to the solution container

Indicates which tubing connects to the patient

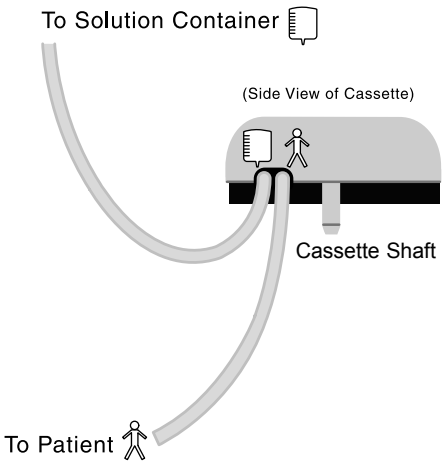
Bolus

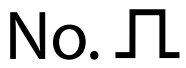
Program Lockout

Bolus Lockout Time in hours : minutes

Bolus Volume in milliliters

Basal Infusion Rate in ml/hr





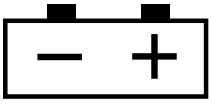
Number of boluses delivered

Number of bolus requests

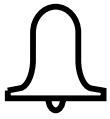
Volume to be Infused

RUN/PAUSE Button

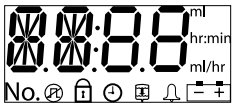
BOLUS Button



Low/Dead Battery Indicator



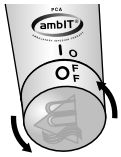
Alarm Indicator

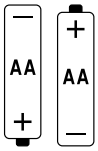


ambIT® PCA Pump Display

Pump Power ON

Pump Power OFF





Battery orientation

Warnings

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

This product should only be used by a physician or by a trained individual under direct supervision of a physician.

Read instructions before use. The Pump must be used strictly in accordance with these instructions.

Safe use of this Pump is the primary responsibility of the user. The user is responsible for monitoring this Pump. Contact clinical/technical support if Pump appears to be operating incorrectly.

All patients should be given a Patient Manual and instructed to read it carefully.

The Pump must be used only by the person for whom it is prescribed.

The patient should never perform any function or push any button unless instructed by their health care professional.

During operation, maintain fluid container at or near the level of the Pump.

Do not allow the Pump to get wet. If the Pump is immersed in any liquid, it must be replaced with a new Pump.

Transport and storage conditions: -7ºC to 70ºC (20ºF to 158ºF), 10% to 90% relative humidity and 500 hPa to 1060 hPa atmospheric pressure.

Operating conditions: 10ºC to 43ºC (50ºF to 110ºF), 10% to 90% relative humidity and 500 hPa to 1060 hPa atmospheric pressure.

Never attempt to open the Pump case. Only the battery cover may be removed when changing batteries. If the Pump is dropped, it must be replaced with a new Pump.

This Pump is not to be used for infusion of blood or blood products.

This pump is not to be used for infusion of life sustaining medications.

Failure to follow manufacturer's instructions while replacing batteries may result in loss of program settings and report data. Dispose of batteries properly after use.

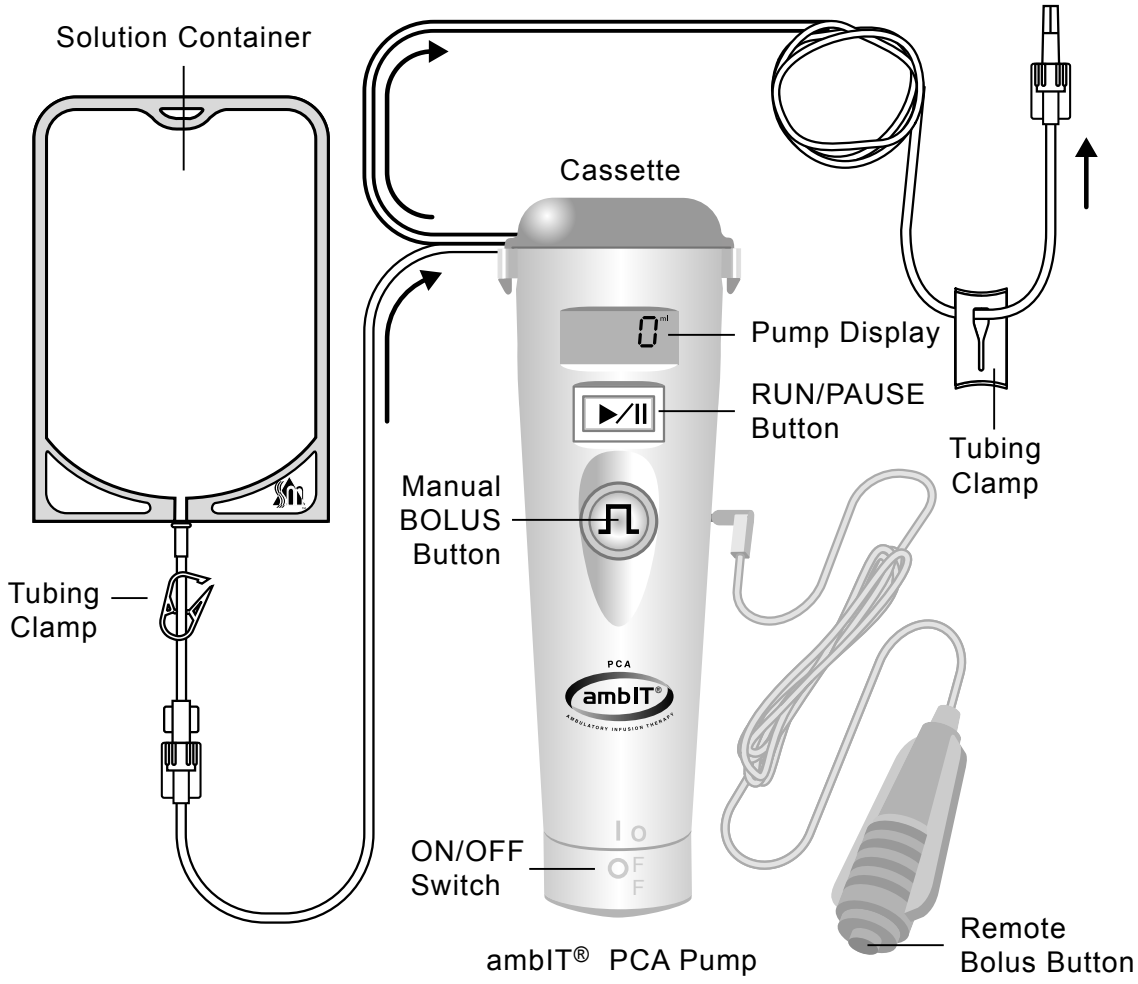
Safety hazards such as under infusion may be associated with external radio frequency interference (RFI) or electromagnetic radiation. Typical equipment which may generate such radiation include x-ray machines, MRI equipment, and any other non-shielded electrical equipment.

Failure to use the approved Sorenson Medical, Inc. remote BOLUS button could result in an inadvertent bolus dose.

ambIT® PCA Pump Description

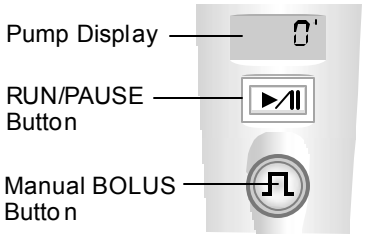
The ambIT® PCA Ambulatory Infusion Pump is intended for the ambulatory infusion of fluids and medications. The Pump has simple controls that are easily operated.

The **RUN/PAUSE** button is located just below the Pump display. This button is used to start, pause or resume the infusion and silence alarms. The **RUN/PAUSE** button toggles between Run and Pause. A blinking green Run light (inside the Bolus button) and "ml" (volume infused) in the Pump display indicate the Pump is infusing. If the infusion is paused, a blinking Pause symbol (II) in the Pump displays and two (2) beeps every four (4) minutes indicates that the Pump infusion has been temporarily stopped. The **BOLUS** button is located below the **RUN/PAUSE** button. When pressed in **RUN** mode the Pump will deliver the programmed bolus dose. During bolus delivery, the green Run light (inside the Bolus button) will double blink.



PCA Bolus Activation

The PCA (Patient Controlled Analgesia) BOLUS button is located on the Pump directly below the RUN/PAUSE button. Every time the BOLUS button is pressed during the infusion, the Pump will beep once. If the bolus dose is permitted, the Pump will begin bolus administration. During bolus infusion, the green Run light will double blink. If the BOLUS button is pressed during the bolus lockout time, the pump will beep once, but no bolus will be delivered.

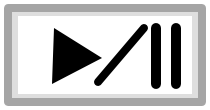


Note:

A remote BOLUS button may also be used. Connect remote BOLUS button to the pump before placing Pump in Run mode.

Normal Operations

During normal operation, the green Run light (inside the Bolus button) will start to blink and the ml (volume infused) will appear in the Pump display.

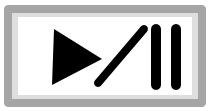


Pause Infusion

To PAUSE the infusion, press the RUN/PAUSE button. The Pump will beep two (2) times, the green Run light will stop blinking and the Pause (ll) icon will blink in the Pump display. If left in Pause, the Pump will beep two (2) times every four (4) minutes.

Note:

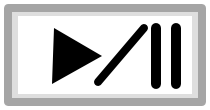
Pause temporarily stops the infusion. While in Pause, the infusion is delayed. This allows for changing the Cassette, solution container, or batteries.



Resume Infusion

To resume the infusion from Pause, push the RUN/PAUSE button.

The display will show the “ml” (volume infused) and the green Run light will start to blink. The infusion will resume at the same point as when the Pump was placed in Pause.

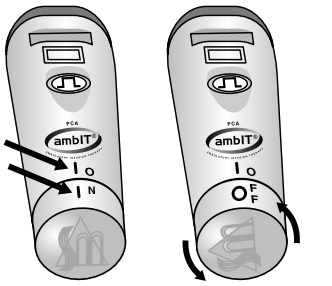


Silence Alarm

To silence an alarm, push the RUN/PAUSE button. When the alarm has been silenced, the Pump will remain in Pause. Once the cause of the alarm has been corrected, press the RUN/PAUSE button to resume the infusion.

Note:

If the Pump alarms due to downstream pressure, and the cause of the alarm is corrected without intervention, the alarm will silence and the Pump will resume the infusion automatically.



Power ON | Power OFF Counterclockwise

Power ON and OFF

To power on the Pump, rotate the battery cover clockwise until the (I) mark lines up with the (I) mark on the Pump.

To power off the Pump:

STEP 1: Place the Pump in PAUSE.
STEP 2: Rotate the battery cover counterclockwise until the (O) mark lines up with the (I) mark on the Pump. (See illustration)

Battery Installation and Replacement

The Pump is powered by two (2) AA alkaline 1.5V batteries.

Caution:

Sorenson Medical has not tested all rechargeable batteries with the pump; therefore we cannot ensure that a specific rechargeable battery will power the pump for a period of time. The battery condition and pump settings will determine how the battery will perform in the pump. For this reason the time before the low battery alarm occurs and the time between low and dead battery alarms is difficult to predict with non-alkaline batteries. We recommend you change the batteries at the end of each therapy.

The Pump memory is designed to retain program settings and infusion history for up to six (6) months without power. Failure to follow manufacturer's instructions while replacing batteries may result in loss of program settings and report data. Do not store batteries in the Pump.

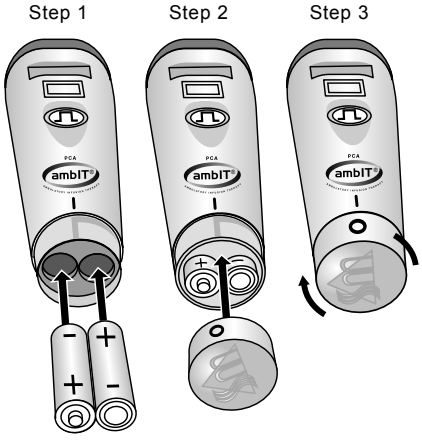
Battery Installation

To install batteries see illustration.

STEP 1: Insert batteries according to illustration

STEP 2: Place battery cover on Pump as illustrated in diagram OFF symbol (O) on cover slightly to left of the (I) mark on Pump).

STEP 3: Rotate battery cover clockwise to the OFF (O) position.



Battery Replacement

To replace batteries:

STEP 1: Place Pump in PAUSE.

STEP 2: Rotate battery cover counterclockwise slightly to the left of the OFF (O) position until the cover stops or meets resistance.

STEP 3: Remove cover and replace batteries as described above.

Resuming Infusion After Battery Replacement

First power Pump on. Pump will be in Pause Mode.

Press the RUN/PAUSE buttone one (1) time. Pump data will scroll and the PAUSE (II) icon will appear in the Pump display.

Press the RUN/PAUSE button a second time to resume to current infusion.

Caution:
Verify the Pump is in Pause mode before removing batteries.

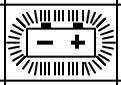
Summary of Operating Controls

To:	Steps to Take	Audible Indicator	Visual Indicator
Start Infusion	Press RUN/PAUSE button	None	Green Run light blinks (inside BOLUS button) and "ml" (volume infused) is in Pump display
Pause Infusion	Press RUN/PAUSE button one time	2 beeps	Pause (ll) icon flashing in display
Silence Alarm	Press RUN/PAUSE button one time	Alarm sound stops	Pause (ll) icon flashing in display
Bolus Delivery	Press BOLUS button one time Note: Patient may use manual or remote BOLUS button.	1 Beep	Green Run light double blinks

Troubleshooting

Problem	Resolution
No display	· Insert fresh batteries · Verify proper battery placement. · Verify Pump power is in the "ON" position
Constant beeping during infusion	Fluid path occlusion · Verify that tubing clamps are open · Check for kink in tubing
Continuous tone	Malfunction · Immediately close tubing clamp · Possible dead battery alarm, replace batteries · Gently press on top of cassette to ensure proper placement · Manufacturer's service/assistance may be required
Blood backed in tubing	· Verify Pump is in Run mode · Notify healthcare professional

Visible and Audible Alarm and Signal Table

Status	Icon	Visual Indicator	Audible Indicator	Comments
Pump Infusing Normally		Green Run light (inside **BOLUS** button) blinking, and “ml” (volume infused) in display.	None	Periodic movement of Cassette gears is normal.
Infusion Paused		“Pause” icon blinking in display. Green Run light off.	2 beeps every 4 minutes	
Infusion Complete		“Bag” icon illuminated	1 long tone followed by 3 short beeps. Repeats every 4 minutes	“Infusion Complete” alert will sound every 4 minutes.
Bolus Infusion	 	Green Run light (inside **BOLUS** button) double blinks. “Bolus” icon is displayed.	1 Beep	1 beep will sound every time the **BOLUS** button is pressed during Run mode.
Occlusion Alarm		“Alarm” icon illuminated with “OCL” in display	Constant Beeping	Press **RUN/PAUSE** button to silence alarm. Press **RUN/PAUSE** button to restart Pump. If unable to resolve (silence) alarm, contact health care professional.
Cassette not Attached to Pump		“MA” and “Alarm” icon	Constant Tone	Press **RUN/PAUSE** button to silence alarm. Gently press on top of Cassette to ensure proper placement. Resume infusion.
Low Battery		“Battery” icon blinking	5 short beeps every 4 minutes	Replace batteries as soon as possible.
Dead Battery	 	“Battery” icon, “Alarm” icon illuminated	Constant Tone	Press **RUN/PAUSE** button to silence alarm. Alarm and battery icons will remain on. Replace batteries immediately.
Malfunction		“MA” and “Alarm” icon illuminated	Constant Tone	Immediately close tubing clamp. See Section 8–Troubleshooting.

GENERAL CARE INSTRUCTIONS

The patient should be careful to protect the Pump at all times. The Pump should not be dropped, stored in freezing -7ºC (20ºF) temperatures, left in direct sunlight or exposed to excessive heat 70ºC (158ºF). The Pump should only be operated between 10ºC and 43ºC (50ºF and 110ºF).

Pump and components should be stored in a dry, cool place until used.

The Pump can be cleaned by wiping its surface with a slightly damp cloth. Use only mild detergent soaps.

To disinfect the Pump, use a cloth slightly dampened with any of the following:

- A fresh solution of one (1) part household bleach to nine (9) parts water.
- 70% Isopropyl alcohol.
- Equivalent disinfectant product.

Warning:

Pump failure may be caused by the application of cleaning solutions other than those recommended by the manufacturer.

Do not immerse the Pump or sterile Cassette in any cleaning solutions.

CUSTOMER ASSISTANCE

For Customer Assistance, please contact your distributor or Sorenson Medical, Inc. at:

Sorenson Medical, Inc.
1375 West 8040 South
West Jordan, Utah 84088-8320, USA

Toll Free: (877) 352-1888
Phone: (801) 352-1888
Fax: (801) 352-1818

e-mail: service@sorensonmedical.com
Web Site: www.sorensonmedical.com

European Representative:
Medical Technology Promedt Consulting GmbH
Altenhofstraße 80
66386 St. Ingbert
Germany

ambIT® PCA Ambulatory
Infusion Pump is a trademark of:

SORENSON MEDICAL

FINDING BETTER WAYS TO CARE FOR PEOPLE™